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Sent: 7/26/2016 12:38:59 PM
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Subject: FRN (attached) for glyphosate SAP review (Oct 18-21) to be released today
Attachments: epa2016_1559.pdf

Daily News

EPA Convening FIFRA SAP To Review Glyphosate's Potential Cancer Risk

July 25, 2016

EPA is convening a meeting of its Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) this fall to review its recent analysis of whether glyphosate, the nation's most commonly-used herbicide, causes human cancers, as recent reviews by other regulatory bodies have drawn conflicting conclusions.

In a [notice](#) scheduled for publication in the *Federal Register* July 26, EPA seeks both nominations of scientists to participate in the Oct. 18-21 review in Arlington, VA, and public comment to inform the SAP's analysis. EPA will seek nominations for 30 days, and has set a preferred deadline for written comments by Oct. 4, though comments will be accepted until the meeting starts.

EPA says it will seek SAP advice on the agency's recent analysis of the potential carcinogenicity of glyphosate. Staff recently reviewed "a substantial amount of data," the notice says, using its draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment" to guide the review.

The plan to seek outside input comes as EPA is facing criticism for its handling of the FIFRA-required registration review of glyphosate and of its efforts to incorporate epidemiological, or human data, into pesticide risk reviews, assessments that in years past have generally relied on animal toxicology studies.

House science panel Chairman Lamar Smith (R-TX), began an investigation this spring into EPA's handling of glyphosate after the agency in April posted its "Cancer Assessment Document: Evaluation of the Carcinogenic Potential of Glyphosate" finding the substance is unlikely to cause cancer and then subsequently withdrew that document May 2.

Smith requested agency documents supporting the withdrawn review, and a source with the committee has said the panel's review is considering the possibility that EPA scientists are split on whether glyphosate causes cancer, and how such a split might affect the agency's registration review of the substance.

In a July 25 statement, Smith faulted EPA for withdrawing its completed review of glyphosate, and argued the agency is putting political considerations ahead of its own science.

"EPA has failed to provide the Committee with a single document responsive to its oversight request on this subject," the statement says. "The Committee will continue to pursue its oversight efforts on this matter to ensure that EPA is using sound science." Environmental groups have long sought stricter EPA oversight of glyphosate, arguing heavy use of the substance, particularly since the advent of genetically-modified crops designed to withstand the substance in the 1990s, poses significant ecological risks, including increasingly resistant weeds.

But focus on the potential human health risks of glyphosate picked up last year after a World Health Organization (WHO) International Agency for Research on Cancer (IARC) March 2015 report found glyphosate probably causes cancer.

Epidemiological Data

EPA cites the IARC review in the notice as well as other recent reviews including a May 2016 conclusion of the Joint Food and Agriculture Organization's Meeting on Pesticide Residues, another branch of the WHO, that glyphosate is unlikely to pose a risk of human cancers through diet. Also, the European Food Safety Authority (EFSA) in November deemed glyphosate unlikely to pose a cancer risk to humans, the notice says.

EPA's notice also describes its own recent analysis of "a substantial amount of data informing the carcinogenic potential of glyphosate," which relied on the agency's draft framework for incorporating epidemiological and incident data in risk assessment.

EPA says the draft guide provides a foundation for assessing multiple lines of evidence and includes a problem formulation component as well as mode of action and adverse outcome pathway frameworks.

Additionally, EPA says, "A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed." The literature review considered epidemiological, animal carcinogenicity, genotoxicity, metabolism, and mechanistic studies.

EPA's use of epidemiological data in pesticide risk assessments has been controversial, with some agency science advisors at an April meeting on EPA's potential ban on the insecticide chlorpyrifos arguing the agency is improperly relying on a single Columbia University epidemiological study that was not designed for regulatory purposes.

For glyphosate, the agency conducted a systematic review to obtain relevant and appropriate open literature studies to inform its review of the pesticide's potential cancer risk, and compared the studies obtained with recent reviews conducted internally and by other international review bodies, including IARC and EFSA.

EPA also conducted a weight of evidence analysis of its multiple lines of evidence, evaluating the strength, consistency, and biological plausibility of the evidence, among other factors.

“The agency will solicit advice from the SAP on the evaluation and interpretation of the available data for each line of evidence and the weight-of-evidence analysis, as well as how the available data inform cancer classification descriptors according to the agency’s 2005 Guidelines for Carcinogen Risk Assessment,” the notice says. -- *Dave Reynolds* (dreynolds@iwpnews.com)

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